



K961820

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Premarket Notification  
Storz Instrument Company

**510(k) SUMMARY OF SAFETY AND EFFECTIVENESS**

The following information is submitted in accordance with the requirements of 21 CFR 807.92:

**Contact Person:** Regulatory Affairs Associate

**Date Prepared:** May 9, 1996

**Proprietary Name:** Storz DP4600 Anterior Intraocular Pressure Control Pack.

**Common/Usual Name:** Ophthalmic microsurgical system accessory pack for anterior intraocular pressure (IOP) control.

**Classification Name:** System, Phacofragmentation (86 HQC).

**Device Description/Intended Use:** The Storz DP4600 surgical accessory pack contains an Anterior Intraocular Pressure (IOP) Tube Set Assembly. This component is to be used as an accessory to the Storz PREMIERE® (K894278, K921460, and K946227) and Storz DAISY™ (K854508) Microsurgical Systems in the maintenance of intraocular pressure (IOP) during anterior segment ophthalmic surgical procedures. The DP4600 is a standard irrigation administration tube set with an additional line that connects the irrigation bottle to an air port on the microsurgical system console. Controlled positive air pressure from the system pressurizes the irrigation bottle and delivers the irrigation fluid at the user-selected rate.

**Predicate Devices:** The proposed Storz DP4600 Anterior Intraocular Pressure Control Pack is substantially equivalent to the existing Storz DP4600 IOP Control Pack (K894278) and to the Storz DP4101 Basic I/A Pack (K953078).

**Predicate Comparison:** A chart comparing the proposed Storz DP4600 to the predicate devices, demonstrating substantial equivalence, is attached.

**Submitted by:**

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## DEVICE COMPARISON CHART

### Storz DP4600 Intraocular Pressure Control Pack

Device	Storz DP4600, modified	Storz DP4600, existing	Storz DP4101 Basic I/A Pack
Intended Use	Controlled Delivery of Irrigation Solution during Anterior Segment Ophthalmic Surgery	Controlled Delivery of Irrigation Solution during Anterior Segment Ophthalmic Surgery	Controlled Delivery of Irrigation Solution and Removal of Aspirant during Anterior Segment Ophthalmic Surgery
Components	IOP Tube Set, with irrigation administration line and filtered air line, and Instruction Sheet	IOP Tube Set, with irrigation administration line and filtered air line, and Instruction Sheet	Irrigation/Aspiration (I/A) Tubing, I/A Test Chamber, Collection Cassette, and Instruction Sheet
Manual Adjustment of Flow?	Yes	Yes	Yes
Flow Control Variable	Irrigation Reservoir Pressure	Irrigation Reservoir Pressure	Irrigation Reservoir Height
Single Patient Use?	Yes	Yes	Yes
Provided Sterile?	Yes	Yes	Yes
Sterilization Method	Gamma Irradiation	Gamma Irradiation	Gamma Irradiation
Packaging	Singly in Tyvek® / PET Pouch, Ten pouches per Box	High-impact Polystyrene Tray with Tyvek® Lid, Six Trays per Box	High-impact Polystyrene Tray with Tyvek® Lid, Six Trays per Box